

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,

Defendant.

C.A. No. 18-823-CFC-JLH


PLAINTIFFS' RESPONSE TO DEFENDANT'S OCTOBER 27, 2020 LETTER

Dated: November 2, 2020

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP 919 N. Market St., 12th Floor
Wilmington, DE 19801
Telephone : (302) 777-0300
Fax : (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Martin J. Black (admitted *pro hac vice*)
Sharon K. Gagliardi (admitted *pro hac vice*)
Brian M. Goldberg (admitted *pro hac vice*)
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
Tel: (215) 994-4000
martin.black@dechert.com
sharon.gagliardi@dechert.com
brian.goldberg@dechert.com

Robert D. Rhoad (admitted *pro hac vice*)
DECHERT LLP
102 Carnegie Center
Suite #104
Princeton, NJ 08540
Tel: (609) 955-3200
robert.rhoad@dehcrt.com

Johnathan D.J. Loeb, Ph.D (admitted *pro hac vice*)
DECHERT LLP
2400 W. El Camino Real, Suite 700
Mountain View, CA 94040-1499
Tel: (650) 813-4995
jonathan.loeb@dechert.com

Blake B. Greene (admitted *pro hac vice*)
DECHERT LLP
300 W. 6th Street, Suite 2010
Austin, TX 78701
Tel: (512) 394-3000
blake.greene@dechert.com

*Attorneys for Plaintiffs Par Pharmaceutical, Inc.,
Par Sterile Products, LLC, and Endo Par Innovation
Company, LLC*

Dear Magistrate Judge Hall:

The Scheduling Order in the case requires Court approval or party permission to serve an expert report after January 20, 2020. D.I. 20, ¶ 11(a); D.I. 148. The parties served numerous reports after that date, culminating in Eagle's service of 63 new pages in 3 new reports on September 16. The relevant chronology is as follows:

Date	Filer/Expert	Pages	Subject
Jan. 20, 2020			Last day to serve reply reports
May 5, 2020	Eagle/Park	1	Supplemental report adding new stability data
May 8, 2020	Par/Kirsch	3	Reply to new Park non-infringement opinions
May 11, 2020			Court hears argument and denies Eagle's motion for leave to file for summary judgment of non-infringement; Pretrial Order filed
June 8, 2020	Eagle/Park	11	Sur-reply to Kirsch May 8 report
July 16, 2020	Par/Kirsch	5	Reply to Park June 8 non-infringement report
Sept 16, 2020	Eagle/Park/Chyall	63	Non-infringement (Park) and invalidity (Park and Chyall) reports
Jan. 11, 2021			Trial Date

The dispute boils down to two issues: (1) whether, and to what extent, supplemental infringement expert reports to address data Eagle generated after the close of fact discovery should be permitted, and (2) whether Eagle should be permitted to use Par's inadvertent late production of sales data and Dr. Kirsch's supplemental infringement reports to offer entirely new invalidity theories. The motion is governed by the *Pennypack* factors. *See Meyers v. Pennypack Woods Home Ownership Assoc.*, 559 F.2d 894, 904-05 (3d Cir. 1977).

Infringement Reports—Background: The patents-in-suit cover formulations with pH values of 3.8 and 3.7-3.9. The parties addressed the pH of Eagle's ANDA product and other matters in three expert reports, culminating with Par's reply report on January 20. Eagle obtained additional stability data from ongoing testing, and after expert depositions had been concluded, Eagle served a supplemental report from Dr. Park (the "May 5 Report") relying on this data. Par responded that it consented to the new report and would provide a reply shortly. Ex. A, 5/7/2020 email. The following day, Dr. Kirsch provided a three page response (the "May 8 Report"), including [REDACTED]

The May 5 and May 8 Reports were submitted to the Court and discussed during the May 11 argument on Eagle's request for leave to file for summary judgment of non-infringement. Eagle expressed no objection to Dr. Kirsch's May 8 Report replying to Dr. Park's May 5 supplemental report, and did not note any dispute in the May 11 Pretrial Order. D.I. 187. The Court denied Eagle's request, concluding that infringement would have to be addressed at trial.

Unhappy with the decision, Eagle began a cascade of supplemental reports, and the case went off the rails. On June 8, 2020, Eagle submitted a new 11 page non-infringement report. This prompted a five-page response from Dr. Kirsch on July 16, 2020. Eagle waited two months, and

then responded with an additional 23 page non-infringement report on September 16, 2020.

May Infringement Reports: Dr. Kirsch's May 8 Report was submitted to and discussed with the Court (D.I. 186, Ex. J) and incorporated in the Pretrial Order without objection (D.I. 187, Ex. 2 at 1). To the extent Eagle had an objection to the three-page May 8 Report, it was waived. Moreover, the Scheduling Order permitted Par the last word on infringement. Eagle offered new data on May 5, and Par provided its response on May 8. The May 8 Report did not include a "new infringement theory," as Eagle asserts—rather, it included his reply to Dr. Park's new opinions. Had the [REDACTED] stability data been available and cited by Dr. Park in his initial rebuttal report, Dr. Kirsch would have provided his three page May 8 analysis in his January 20 reply report, and that would have closed the infringement reports.

June/July Infringement Reports: After losing its bid for summary judgment, Eagle waited a month and filed a new non-infringement report on June 8. Eagle did not seek permission from the Court to do so. In an abundance of caution, Par filed a short responsive report on July 16. Given the imminent trial date and Eagle's lack of diligence, the Court should deny Eagle's request to accept the June 8 Report. Par's July 16 Report and everything that followed would then be moot. In the alternative, the Court should allow both reports and stop the cavalcade of reports at that point. The case is hurtling towards trial, and Eagle's proposal to take further expert depositions just two months before trial would be highly prejudicial, particularly given that Par is in the midst of completing expert discovery and the pretrial process for the other case to be tried together with this one on January 11 (against Amneal). Eagle cannot seek summary judgment, lose, redo its expert reports, and then start all over again.

September Infringement Report: Although Par is entitled to the last word on infringement, Eagle served a new 23 page non-infringement report on September 16. There is no justification for this report, as Par is entitled the last word on infringement, and Eagle does not even try to explain why it waited more than two months to serve it. No good cause is demonstrated in Eagle's motion for admitting this report, much less the long delay between July and September.

September Invalidity Reports: Eagle asserted anticipation and obviousness in relation to Par's prior art Pitressin product, singling out [REDACTED] and a few others in its opening invalidity reports. For example, Dr. Park analyzed the stability data for [REDACTED] and opined that the lot was "anticipatory" based on its pH. *See, e.g.*, Ex. B, Park Opening Report ¶¶ 123, 125. Dr. Chyall cited that same stability data. Ex. C, Chyall Opening Report ¶¶ 65, 224 (citing PAR-VASO_0108645). Dr. Park assumed the fact [REDACTED] Ex. B, App. 1 at 1, 8, 15, 20, 22; *see also id.* ¶ 127 ([REDACTED])

[REDACTED]). In his rebuttal validity report, Dr. Kirsch challenged the sufficiency of Dr. Park's proof that [REDACTED] satisfied claim limitations other than pH, such as the degradation, impurity, and storing limitations. Ex. 13 ¶ 112. In reply, Dr. Park maintained his opinion that [REDACTED] but presented no opinions about [REDACTED] satisfying the other claim limitations. *See* Ex. D, Park Reply ¶ 109 [REDACTED]

[REDACTED]. That closed expert technical opinions on issues of alleged invalidity.

In addition to the technical opinions, there was a factual question regarding the prior art status of [REDACTED] whether it was on sale and therefore qualified as prior art.

Ex.

15. Par promptly produced the data to Eagle and voluntarily agreed to stipulate as to authenticity of the sales data (D.I. 204). *Id.*

Without Par's consent and without seeking leave from the Court, Eagle then served supplemental invalidity reports for Dr. Park (32 pages) and Dr. Chyall (8 pages) on September 16. Exs. 16, 18, 19. The reports contain new opinions regarding Pitressin and a different prior art reference (Original Vasostrict), including by way of example only the following:

- Opinions that [REDACTED] allegedly meets or renders obvious limitations other than pH. *See, e.g.,* Ex. 18 ¶¶ 28-29, 55-74, 77-84, 86, 91, 94.
- [REDACTED] and other hypothetical Pitressin and Original Vasostrict lots. *Id.* ¶¶ 42-52.
- Additional theories regarding alleged lack of criticality of the claimed pH values. *See id.* ¶¶ 53-54, 57-59, 72-73, 83; Ex. 19 ¶¶ 8-15.

There is no justification for these additional technical opinions. Par has stipulated that [REDACTED] was on sale, thus narrowing the factual issues for trial. Eagle cannot use that as a jumping-off point to rewrite its expert opinions and provide dozens of new pages on invalidity. Eagle's invalidity opinions regarding [REDACTED] served during the expert phase are admissible, but the detailed new opinions on that lot and on Original Vasostrict should be excluded.

Secondarily, Eagle argues that the new invalidity reports are justified by Dr. Kirsch's supplemental infringement reports. The argument is pretextual. Eagle waited until September to make the new arguments—months after Dr. Kirsch's May and July reports—which shows that they were not offered in response to his supplemental reports. Dr. Kirsch's 8 pages of responsive infringement opinions hardly justify 40 pages of new invalidity opinions. Dr. Park was also free to [REDACTED] at the time of his opening report, but opted against it.

Eagle's experts could and should have addressed during expert discovery the opinions newly raised in their proposed supplemental reports; they should not be allowed to try to fill evidentiary gaps through supplementation well after the close of discovery and the Pretrial Order filing. *See Robocast, Inc. v. Apple Inc.*, No. CV 11-235-RGA, 2014 WL 334199, at *1 (D. Del. Jan. 28, 2014) (“Supplementation of an expert report . . . does not give license to sandbag one’s opponent with claims and issues which should have been included in the expert witness’ report.”).

In summary, under the *Pennypack* factors, the Court must weigh prejudice, ability to cure, trial disruption, bad faith/willfulness, and importance. Judge Connolly has now set the case down for trial on January 11, and leave to introduce new opinions, much less conduct new depositions, should be granted sparingly. This case is in a decidedly messy position, and we need to return to regular order. Given that reality, the Court should (a) permit the May 5 and May 8 reports already submitted to the Court without objection, (b) permit the brief June/July infringement reports or in the alternative admit only the June Eagle report and stop the train of infringement reports at that point, and (c) deny the September invalidity reports, which are pretextual.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (Via E-Mail)